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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,519	02/13/2004	Garratt W. Ponder	BARR.10004	8918

45473 7590 03/09/2007  
HUTCHISON LAW GROUP PLLC  
PO BOX 31686  
RALEIGH, NC 27612

EXAMINER
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BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

**Application No.**

10/779,519

**Applicant(s)**

PONDER, GARRATT W.

**Examiner**

Barbara P. Badio, Ph.D.

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-21 is/are allowed.
- 6) ☒ Claim(s) 1,4 and 5 is/are rejected.
- 7) ☒ Claim(s) 2,3 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 01/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

**First Office Action on the Merits**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Koizumi et al. (Chem. Pharm. Bull., 1996).

Koizumi et al. teaches the ozonolysis of 6,7-epoxide-3-oxo-androstanes with the production of the corresponding 2-oxasteroids (see the entire article, especially page 2162, Chart I; page 2163, col. 1, compound 3 and page 2164, compound 12). The process taught by the reference is encompassed by the instant claim.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Rasmusson et al. (J. Med. Chem., 1984).

Rasmusson et al. teaches the preparation of A-ring heterocyclic steroid from 3-keto-4-ene-precursors by oxidation with ozone (see the entire article, especially

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Abstract; page 1701, compound 40). The process taught by the reference is encompassed by the instant claim.

4. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Cabaj et al. (US 2003/0032817).

Cabaj et al. teaches the production of oxandrolone from mestanolone comprising the ozonolysis of  $17\beta$ -hydroxy- $17\alpha$ -methyl-5- $\alpha$ -andro-1-ene-3-one (see the entire article, especially Figure 1 and Example 11). The process taught by the reference is encompassed by the instant claim.

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabaj et al. (US 2003/0032817), Koizumi et al. (Chem. Pharm. Bull., 1996) and Rasmusson et al. (J. Med. Chem., 1984).

Each of the cited prior art teaches the production of a 2-oxasteroid comprising the ozonolysis of a 3-oxo androstane derivative (see the entire disclosure of each

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reference, especially Cabaj, Figure 1 and Example 11; Koizumi, page 2162, Chart I and pages 2163-2164, compounds 3 and 12; Rasmusson, page 1701, compound 40).

The instant claims differ from the reference by reciting additional compounds not exemplified by the references. However, the use of analogous reactants in a known process is considered prima facie obvious. *In re Durden*, 226 USPQ 359 (1985). Once the general reaction has been shown to be old, the burden is on Applicants to present reasons or authority for believing that a group on the starting material would take part in or affect the basic reaction and, thus, alter the nature of the product or the operability of the process. In looking at the instant claimed process as a whole, as stated in *In re Ochiai*, 37 USPQ2d 1127 (1995), the claimed process would have been suggested to one skilled in the art.

Claims 4 and 5 further differ from the cited prior art by reciting temperature range and reaction time not disclosed therein. However, changes in the reaction condition, such as temperature and reaction time, in order to optimize a reaction is routine in the chemical art and, thus, is prima facie obvious in the absence of a showing of criticality. Thus, the instant claims are not patentable over the cited prior art.

#### ***Allowable Subject Matter***

7. Claims 7-21 are allowed.

8. The following is a statement of reasons for the indication of allowable subject matter:

The prior art teaches the reaction of 3-oxo androstane derivative with ozone and the production of a 2-oxasteroid derivative. However, the prior art starting compounds, unlike those of the claims 7-21 of the present invention, are unsaturated steroid derivatives, for example, 1-ene steroids. The prior art lacks motivation to utilize a saturated steroidal starting compound. In fact, Cabaj teaches the conversion of said saturated derivative, i.e., mestanolone, to the corresponding 1-ene derivative before reacting with ozone (see Figure 1 and Example 11 of Cabaj).

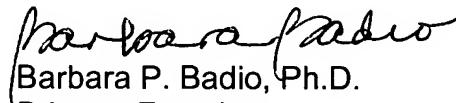
#### ***Telephone Inquiry***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
March 5, 2007